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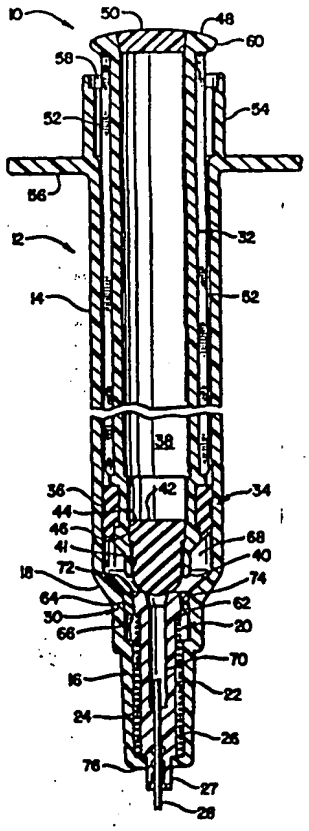
(54) Title: TAMPERPROOF RETRACTABLE SYRINGE

(57) Abstract

A tamper proof retractable non-reusable syringe (10) has a one piece hollow outer body (12) with a barrel (14) for a slidable plunger, a transition zone (18) and a smaller diameter nose portion (16). An elongated needle holder (22) and spring (24) combination is installed from the rear of the outer body, guided into the nose portion and held by cooperating inwardly and outwardly facing surfaces oriented in the direction of retraction at the most constricted part of the transition zone where the nose begins. The plunger has an opening with a dislodged stopper (42) for receiving parts of the retraction mechanism (20). The stopper and the head of the needle holder are of significantly reduced diameter from the injection fluid chamber to resist blowing out prematurely. In one embodiment the head of the needle holder is surrounded by a separable retainer member which is slide removed by contact with the tip of the plunger after the stopper is mostly or fully removed to avoid cumulation of force required for retraction after the injection.



# TAMPERPROOF RETRACTABLE SYRINGE

~~CROSS REFERENCE TO RELATED APPLICATION~~

~~This application is a continuation-in-part of copending patent application serial number 08/438,954 filed May 11, 1995 by the same inventor entitled Tamperproof Retractable Syringe for which benefit is claimed under 35 U.S.C. §120.~~

## FIELD OF THE INVENTION

This invention relates to a medical device, and more particularly to a retractable syringe suitable for mass production and assembly having a low triggering force and high blowout pressure which is nonreusable after one use.

## BACKGROUND OF THE ART

A major cause to the spread of AIDS in the general population is the presence of IV drug users who share and reuse hypodermic syringes to inject drugs. Infection can be spread from AIDS patients in hospitals and medical facilities through accidental needle sticks from needles used on infected patients. Used syringes with extended needles present a risk to medical personnel and sanitation employees and others in the disposal chain.

The gravity of the threat posed by AIDS and the fact that the main vector of the spread of the dreaded disease is through reuse of syringes by IV drug users has resulted in intense

in the form of coil tubing and vary significantly from straightness after they are cut to length. This leads to difficult assembly problems if the needle must be passed through a small opening. The extremely sharp tip will catch the edge of a hole and jam the production line.

The rare prior art that employs a front mounted retraction mechanism in a one-piece barrel with a plugged hollow plunger, Tsao U.S. Pat. No. 5,084,018, among other things does not show reduced barrel area to prevent excessive blowout pressure, employs engaging flanges to secure all retraction parts, requires concurrent distortion of internal parts and flanges to effect release, cumulating in excessive force required to retract and requires ventilation holes because of a compartmented barrel.

The prior art has not produced a retractable nonreusable tamperproof syringe for mass production and assembly which is simple, reliable, cost effective, easy to use and retract, looks like a conventional syringe, has few parts which are easy to make and assemble, is not temperature sensitive and not subject to danger of premature retraction.

The prior art has not recognized a retraction mechanism with separable parts that relies entirely on clamping force or friction at a smooth walled reduced diameter transition zone in the barrel with mating lands which are slidably or separably released in response to relatively low thumb pressure while having resistance to premature retraction and high blowout pressure resulting from high pressure produced in the fluid chamber during an injection. The prior art has not recognized that such a structure can be molded as a one piece outer body over a core that can be pulled out from behind allowing the retraction mechanism to be easily pushed into place from behind, steered by the narrow nose portion. Neither does the prior art in such a combination realize the desirable non-cumulation of forces resisting retraction in order to minimize the thumb force required, having a most simple tamperproof feature and the fewest

holder in opposition to the retraction force applied to the needle holder by the spring. The parts are circular in cross section.

The outwardly facing surface on the circular head of the needle holder is slightly greater in diameter than the circular inward facing surface in the wall at the most constricted portion where the nose begins. The needle holder is thus clamped in position by hoop stresses induced in the outer body and held in position by frictional holding force. The needle holder is released in response to depression of the plunger to a retraction position. Retraction occurs in response to thumb force on the plunger when a portion of the plunger passing into the transition zone separates at least a portion of the inwardly and outwardly facing cooperating surfaces thereby reducing the holding force on the needle holder to an amount less than a retraction force on the needle holder produced by the spring whereby the needle holder is retracted into the cavity a distance sufficient to withdraw an injection needle, attached to the needle holder, into the outer body.

In one embodiment, the head of the needle holder is a two part head comprising an inner head surrounded by a separable retainer member wherein the outer surface of the retainer member is the outwardly facing surface with cooperates with the inwardly facing surface in the wall to retain the needle holder in an unretracted position at the most constricted part of the transition zone where the nose begins. The retainer member is a ring member coupled to the inner head along a sliding interface oriented in the direction of retraction with a friction force which exceeds the retraction force provided by the spring. The front of the needle holder is grounded in the nose portion against forward movement. The plunger head

ring during an actual injection. High blowout pressure resistance is obtained because the retainer ring is mounted in the most constricted portion of the barrel where the nose begins which significantly reduces the amount of area exposed to fluid pressure. The smaller retainer ring allows the use of a small needle holder such that the opening in the plunger and the stopper can be only a fraction of the cross sectional area of the fluid chamber below the plunger head. The ratio of the greatest cross sectional area of the variable chamber and that of the dislodgeable stopper or the ring member are selected so that the maximum expected thumb force on the plunger during an injection will produce a maximum pressure in the chamber which will generate a blowout force on the stopper and retainer member slightly less than the amount of dislodging force necessary to dislodge the stopper and retainer member during retraction. This ratio should be at least two to one, or more preferably three to one or more, in order to ensure against premature blowout of the stopper or retainer ring.

In an alternate embodiment, the fewest number of easily made separate parts are used in a retractable syringe. The alternate embodiment has a similar stopper in the head of the plunger and a similar needle holder and spring combination with mating cooperating inwardly facing and outwardly facing interengaged surfaces at the most constricted part of a transition zone where the nose begins. In the alternate embodiment, there is no retainer ring around the head of the needle holder. Instead a tiny ramp is provided at the transition zone or adjacent the transition zone whereby the head of the plunger gently spreads the barrel outwardly while dislodging the stopper thereby reducing the clamping or friction force on the head of the needle holder provided by the wall of the outer body. The holding force is thereby reduced below the retraction force provided by the compressed spring and the needle holder is ejected into the cavity of the plunger carrying the dislodged stopper along with it.

Figure 3 is the syringe of Figure 2 wherein the plunger has been further depressed to a retraction position, retraction has occurred and the cap at the back of the plunger is closely received in an opening at the back of the outer body;

Figure 4A is a partial cross section on the central axis of an alternate tamperproof opening in the back of the outer body prior to retraction;

Figure 4B is the structure of Figure 4A with the plunger in the retracted position received in an opening at the back of the outer body;

Figure 5 is a cross section along the central axis of a simplified alternate syringe structure without a retainer member around the needle holder, which is released by separation of the friction surfaces, shown in the plunger position which represents the end of an injection cycle;

Figure 6 is the syringe structure of Figure 5 wherein the plunger is further depressed to dislodge the stopper and begin to release the friction surfaces just prior to retraction;

Figure 7 is the syringe structure of Figure 6 with the plunger further depressed beyond the position of Figure 6 to the retraction position where retraction has occurred and the cap is secure within an opening in the back of the hollow outer body.

~~Figure 8 is a schematic longitudinal cutaway view in elevation through the center of the two part head showing how a tack weld can be applied to simultaneously seal and hold the retainer ring in place on the needle holder.~~

## DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

In the description that follows, like parts will be referred to by the same reference numerals. Parts with a subscript letter are mean to illustrate a minor variation of a part with the same number. The drawings are enlarged significantly in order to show the details of the invention but generally reflect the true scale which is contemplated. The parts as shown are

plunger is depressed to the retracted position. An alternate arrangement is shown in Figures 4A and 4B in which barrel 14 is extended longitudinally, if necessary, so that end cap 48 fits closely within an opening at the back of the barrel where the finger grips are. Figure 4B shows the tamperproof position with the plunger in the retracted position. It should be noted that depending on the relationship of the inside diameter of the barrel and the diameter of the end cap, the end cap could instead be received right inside the opening at the back of the barrel . Regardless of how the end cap in back of the outer body and barrel are configured, the plunger can no longer be grasped after retraction has occurred because end cap 48 is depressed into an opening.

The wall of outer body 12 and head 30 of the needle holder have mating cooperating smooth surfaces which hold needle holder 22 in the position shown in Figure 1 with spring 24 compressed. Nose 16 has a reduced diameter relative to the barrel. The outer body has a most constricted part where head 30 of needle holder 22 is engaged and held. The outer body has an inwardly facing surface 62 at the most constricted part of the transition zone where nose 16 begins. Similarly, head 30 has an outwardly facing surface 64 configured to cooperate with inwardly facing surface 62 to produce a holding force on needle holder 22 when the retraction mechanism is installed in the nose from the rear. Mating surfaces 62, 64 constitute a sliding interface oriented in the direction of retraction, which seals nose 16. Mating surfaces 62, 64 are preferably friction surfaces which have an interference sliding fit to apply a frictional holding force which holds needle holder 22 in position by friction between the mating parts. It is within contemplation of the invention that one or more of the cooperating interface surfaces could employ a coating or adhesive bond which is ruptured or released when the mating surfaces or lands are separated or moved relative to each other.

pressure in chamber 68 expected to result from the maximum expected thumb force applied to cap 48 during an injection. This ratio is preferably about two to one and more preferably about three to one or more so that the holding force holding the retraction mechanism in place can be kept at a comfortably low level while the blowout pressure remains high.

Dislodgeable stopper 42 has a similar blowout problem to recognize. The front and middle portion of stopper 42 are relieved slightly from opening 41 such that the fluid pressure in chamber 68 is directed against the cross sectional area at cooperating lands 44, 46 and could cause stopper 42 to blowout. A frictional holding force is generated at the lands 44, 46 which may be called a dislodging force which must be overcome to slide stopper 42 rearwardly before retraction. The ratio of the maximum cross sectional area across the interior of variable chamber 68 to the maximum cross sectional area of stopper 42 exposed to pressure in chamber 68 are selected so that the maximum expected thumb force on plunger 32 during an injection will produce a maximum force slightly less than the amount of dislodging force necessary to dislodge the stopper so that stopper 42 will not blowout during an injection. This ratio is preferably not less than about two to one, more preferably three to one or more, whereby a force of about eighteen pounds on the plunger, for example, would produce a pressure generated force of only about nine or six pounds, respectively, on the stopper, so that the stopper can be easily dislodged in advance of retraction at the end of the injection cycle but will not blowout during an injection. The stopper is dislodged after the injection by thumb force applied to the stopper by movement of the plunger.

The components used for retraction are arranged to avoid cumulation of force during the retraction sequence. In Figure 1, stopper 42 has a forward extension beyond tip 40 which allows full thumb pressure to be applied to the stopper before any other portion of the retraction mechanism is engaged. The amount of forward extension beyond tip 40 is related

the retraction direction of somewhere around a half pound. In use the needle is pushed against a rubber seal in a vial so the needle holder must resist a resulting backward force without being dislodged during the filling operation. This requirement and blowout pressure limits the low end of the holding force on the needle holder.

Referring again to Figure 2, it can be seen that further depression of the plunger beyond the second position of Figure 2 dislodges retainer ring member 66 along the sliding interface 74 provided by the outer surface of inner head 72 and along the inwardly facing friction surface 62. As the amount of remaining engaged interface is reduced, the amount of force required to continue moving retainer member 66 off needle holder 22 is reduced and the small remaining engagement area 80 between lands 44, 46 of the plunger and stopper preferably cause stopper 42 to be dislodged before needle holder 22 is released. When the remaining residual friction force during continued depression of the plunger becomes less than the retraction force provided by compressed spring 24, the retraction position of Figure 3 is reached whereby retraction occurs.

When retraction occurs needle holder 22 moves through opening 41 into cavity 38. The uncompressed length of spring 24 is selected to provide backward movement sufficient to withdraw an injection needle 28 fixed in front portion 26 entirely within outer body 12, carrying dislodged stopper 42 with it. At the same time, cap 48 enters opening 58 of the barrel with peripheral edge 60 closely confined, in order to prevent tampering after retraction. It is immaterial whether cap 48 moves into the opening at the instant of retraction or after retraction has already occurred because the movement is automatic due to the continued thumb force applied to trigger the retraction. Sufficient unengaged length of inwardly facing friction surface 62 is provided so that retainer member 66 can move downwardly a sufficient distance to reach the retraction position of Figure 3. After retraction, retainer member 66 preferably

~~rubber seal of a vial in preparation for use. The bridging portion may be formed by "tack"~~ welding the raised portion 73 to the inner surface of the ring 66a or by providing any other form of frangible bridging portion that holds the separable ring member 66 and needle holder head 72a together. It is required that however done, the bridging portion must also serve as a seal between the facing surfaces of the ring member and inner head so that fluid under pressure cannot pass from chamber 68 through gap 77 to reach the nose portion of the device. All fluid must pass through fluid passage 70.

It can be seen that when the position of Figure 2 is reached the front tip 40 of the plunger presses against retainer ring 66a after stopper 42 is almost dislodged and uncouples the retainer ring 66a from the inner head 72a of needle holder 22a. Any tack weld connecting the separable parts at the bridging portion is ruptured, fractured or otherwise separated so as to separate retainer ring 66 a from inner head 72a thus releasing needle holder 22a from further restraint. They and the force applied by spring 24 causes retraction to occur much as before described and shown in Figure 3.

It is believed that the increased diameter of the raised portion 73 should be within the range of about 1 to 8 thousandths of an inch which may be dictated by the ability of the molding equipment available to produce a consistent bridging portion without defects. It is believed that it may be desirable to employ different polymeric materials for the retainer ring and needle holder to facilitate tack welding, such as a suitable polyvinyl chloride (PVC) for the retainer ring and a suitable polycarbonate plastic material for the needle holder. One way to couple these two parts may be to assemble them and expose them to a temperature of about 120°C for twenty minutes or so to allow some diffusion or incipient melting to occur where they touch. The raised portion creates a high unit pressure where it comes into contact with ~~the inwardly facing surface of retainer 66a. Sonic welding could also be employed. A~~

The outer portion of tip 110 may be equipped with an angled surface 122 designed to cooperate with a small ramp surface 124 located in the vicinity of transition zone 90. The wall of outer body 84 and head 102 of the needle holder have mating cooperating friction surfaces which frictionally hold needle holder 102 in the position shown in Figure 5 with spring 96 compressed. Nose 88 has a reduced diameter relative to barrel 86. The outer body has a most constricted part where the head 102 of needle holder 94 is frictionally engaged. The outer body has an inwardly facing surface or land 126 at the most constricted part of the transition zone where nose 88 begins. Similarly, head 102 has an outwardly facing friction surface 128 configured to cooperate with inwardly facing surface 126 to produce a frictional holding force on needle holder 94 when the retraction mechanism is installed in the nose from the rear.

Mating surfaces 126, 128 constitute a sliding interface oriented in the direction of retraction, which seal nose 88. Mating surfaces 126, 128 are preferably smooth friction surfaces which have an interference sliding fit when needle holder 94 is installed from the rear whereby a frictional holding force holds needle holder 94 in position by friction between land 126 and head 102 of needle holder 94. It is within contemplation of the invention that one or both of these surfaces could have a coating or adhesive bond which is ruptured when the mating surfaces are separated to release the needle holder.

Head 106 provides the upper boundary for a variable fluid chamber 130 below head 106. Needle holder 94 has a fluid path 132 in fluid communication with chamber 130 and needle 28. Needle holder 94 is releasably coupled at surfaces or lands 126, 128 with a holding force that exceed the retraction force applied to the underside of head 102 by the end of compressed spring 96. A reduced diameter portion 134 of needle holder 94 protrudes through an opening in front 136 of nose 88. Blowout pressure is not a factor with respect to

94 to block fluid path 132. Further depression of plunger 104 toward the position of Figure 6 mostly or fully dislodges stopper 114 and begins spreading barrel 84 at the transition zone by sliding contact between head portion 106 and ramp 124. Ramp 124 is a very small inwardly extending annular thickening of the wall of barrel 86 which can take many shapes or forms. For example, ramp 124 may be a small step 125 in the wall which continues vertically downward as indicated by the dotted line, which is somewhat exaggerated in Figure 5.

The barrel is flexible and is spread outwardly a slight amount to the position of Figure 6 just prior to retraction. Here the mating surfaces 126, 128 are separated an amount which reduces the clamping force on the needle holder 94. The spreading shown in Figure 6 is greatly exaggerated for illustration. It is estimated that an expansion of only about four thousandths of an inch is sufficient to release needle holder 94 from nose 88. By slight further depression of the plunger from the position of Figure 6 to the retracted position of Figure 7, retraction occurs when the retraction force applied by spring 96 exceeds the remaining holding force on needle holder 94. Needle holder 94 then moves through opening 112 into cavity 108 along with a portion of spring 96. The uncompressed length of spring 96 is designed to provide sufficient backward movement to withdraw an injection needle 28 fixed in front portion 94 and carry dislodged stopper 114 with it. At the same time, cap 42 enters opening 138 at the rear of a barrel extension 54 where the peripheral edge is closely confined in order to prevent tampering after retraction.

The location and configuration of ramp 124 is arranged to avoid cumulation of force required during the retraction sequence. Most of stopper 114 should be dislodged by thumb pressure on plunger 104 before significant resistance develops as angled surfaces 122 begin pushing outwardly on ramp 124. The selection of the location of ramp 24 and the angle of

outer body and syringe plunger are preferably made from conventional plastic material used for syringes, which has some flexibility. The tolerances on the diameter of mating facing surfaces between the head of the needle holder and the barrel and between the stopper and head of the plunger are not critical in order to maintain a consistent holding and dislodging force. This is believed to be because increasing interference fit increases the frictional holding force only up to a point and then the surrounding wall simply expands a small amount or the internal parts are compressed a small amount without a corresponding increase in the longitudinal force required to move the retainer member or plug member in the retraction direction. It is a desirable self correcting mechanism which is a cost and quality benefit in making the parts. It is believed that a plastic retainer member could be used and the same self limiting frictional holding force would be obtained.

In the best mode the stopper and the ring member are preferably made from a thermoplastic rubber material designated number 181-55 available from Advanced Elastomer Systems, 540 Maryville Centra Drive, St. Louis, Missouri and sold under the trade name Santoprene®. It is said to have a characteristic hardness around 55 on the Shore A durometer scale which allows for the right amount of resistance to compression, fluid resistance such that the material does not swell when in contact with most fluids, environmental stability allowing the friction and sealing properties to remain non-temperature sensitive, good property retention after aging and excellent property retention after sterilization by all accepted methods. The plunger seal around the head of the plunger is conventional.

The parts are few in number and easily mass produced. The alternate embodiment has the fewest number of separate parts of any tamperproof retractable syringe. The plunger has a one piece hollow outer body with a transition zone and a narrow nose portion. The internal

openings where slight misalignment could cause hangups. The head of the needle holder simultaneously acts as a seal as well as a holding device such that no seal is required at the tip of the nose and no ultrasonic welding of separate parts is required.

There is no necessity for using internal locking teeth of any kind. No locking teeth are needed to hold the retraction mechanism or to lock the plunger after retraction. Locking teeth present difficult molding and quality control problems, tend to be temperature sensitive and tend to require a larger diameter barrel which increases premature blowout problems. In addition to the non-reusability provided by separation of the retainer ring from the head of the needle holder and dislodgement of the stopper, the plunger is not accessible after retraction because it is depressed within an opening at the back of the outer body. This additional tamperproof feature is provided in a one piece body without the necessity for hooking anything or twisting anything. The easily made and installed force fit plug at the back of the retraction cavity prevents access to the retracted components. ~~The Federal government has rights in the invention under 35 U.S.C. §203. The Federal government has a nonexclusive, nontransferable irrevocable, paid up license to the invention.~~

retraction occurring in response to thumb force on the plunger when a portion of said plunger passing into said transition zone separates at least a portion of said inwardly and outwardly facing surfaces and thereby reduces the holding force on the needle holder to an amount less than the retraction force whereby the needle holder is retracted into said cavity a distance sufficient to withdraw an injection needle into the outer body.

2. The tamperproof retractable syringe of claim 1 wherein the inwardly facing surface in the wall and the cooperating outwardly facing surface on the needle holder are friction surfaces which cooperate to produce said holding force on said needle holder as a frictional holding force.

3. The tamperproof retractable syringe of claim 2 wherein said frictional holding surfaces comprise a linear interface aligned in the direction of retraction.

4. The tamperproof retractable syringe of claim 1 wherein the plunger has a graspable end cap for depressing the plunger and a length selected to allow the end cap to enter an opening of the barrel when the plunger is depressed to the retraction position, in order to prevent tampering after retraction.

5. The tamperproof retractable syringe of claim 1 wherein the needle holder and the most constricted part of the transition zone where the nose begins comprise a lower boundary of a variable fluid chamber below the plunger head and the needle holder has a fluid path for injection fluid opening into the variable chamber.

6. The tamperproof retractable syringe of claim 5 wherein the plunger head has a tip with an opening sealingly closed by a dislodgeable held stopper which slides relative to the plunger in response to dislodging force applied by depression of the plunger at the end of the injection cycle before retraction occurs.

direction of retraction, with a holding force which exceeds said retraction force, the outer surface of said retainer member having said outwardly facing surface configured to cooperate with said inwardly facing surface to produce said holding force on the needle holder when the retraction mechanism is installed in the nose.

13. The tamperproof retractable syringe of claim 12 wherein said ratio of the greatest cross sectional area of the variable chamber to the area of the retainer member exposed to fluid is selected so that the retainer member has a high blowout pressure higher than the maximum pressure expected as a result of maximum expected thumb force on the plunger and a low frictional holding force to be overcome during retraction so that the thumb force required to trigger retraction is comfortably and substantially lower than said maximum thumb force expected.

14. The tamperproof retractable syringe of claim 13 wherein the ratio of the greatest cross sectional area of the variable chamber to the cross sectional area of the retainer member exposed to fluid in the variable chamber is not less than about two to one so that high blowout pressure can be resisted while retaining a relatively low force on the plunger necessary to cause retraction.

15. The tamperproof retractable syringe of claim 2 wherein the head of the needle holder is a two part head comprising a head surrounded by a separable retainer member coupled with a friction force which exceeds said retraction force along a sliding interface oriented in the direction of retraction, the outer surface of said retainer member being said outwardly facing friction surface which cooperates with said inwardly facing friction surface to retain said needle holder in an unretracted position at the most constricted portion of the transition zone where the nose begins.

pressure which will generate a force on the stopper slightly less than the amount of dislodging force necessary to dislodge the stopper so that the stopper will not blowout during an injection.

22. A tamperproof retractable syringe structure for injecting fluid into a patient comprising:

a syringe body having a wall forming an elongated barrel portion with a smaller nose portion in front and a transition zone between the barrel portion and the nose portion;

a moveable plunger in the barrel portion having a front end and a back end, the plunger having a head at the front end in sliding sealed contact with the interior of the barrel, a cap at the back end for applying thumb force to the plunger, and a cavity for receiving retractable parts;

a retraction mechanism disposed in the nose portion of the syringe body having retractable parts comprising a releasable needle holder and needle frictionally held by the wall of the syringe body with the needle extended from the nose portion, a biasing element applying a retraction force to the needle holder and a fluid path traversing the needle and needle holder;

the head of the plunger having an opening into said cavity, sized to receive the retractable parts and a releasable stopper extending from said opening, the stopper sealing the interior of the plunger from injection fluid stored in a variable chamber defined in the barrel between the retraction mechanism and the head of the plunger;

the plunger being depressible to a first position to expel injection fluid from the variable chamber through the fluid path in response to thumb pressure on said cap, said first position comprising the end of an injection;

force on the stopper and retainer slightly less than the amount necessary to dislodge them so that they will not blowout during an injection.

27. The tamperproof syringe of claim 26 wherein said ratios are not less than two to one.

28. A tamperproof retractable syringe structure having low retraction force comprising:

a hollow syringe body having an elongated barrel portion extending between a nose portion adapted to support a needle holder and a rear portion having an opening for receiving a plunger from the back of the body;

an elongated plunger having a leading head end in front and a trailing back end provided with an end cap for pressing, the head end having an opening in front leading to a hollow cavity in the plunger extending rearwardly toward the back end, the head end being receivable through the opening in the rear portion of the syringe body and being movable in sliding sealed contact with the interior of the barrel;

a frictionally held dislodgeable stopper extending in sealing relation from the opening in the head end of the plunger whereby an upper boundary of a variable chamber for injection fluid is formed below the head of the plunger in the barrel of the syringe;

a needle holder and needle releaseably mounted in the nose portion of the syringe body with the needle extended, the needle holder having a elongated stem portion with a front end grounded against forward motion and a spaced apart enlarged head being releasably held in the nose portion of the syringe body by means of frictional force caused by constricting forces imposed thereon by the nose portion of the syringe body, the enlarged head of the needle holder defining a lower boundary of said variable chamber;

30. The tamperproof syringe of claim 29 wherein the biasing element is a spring loosely surrounding the stem portion of the needle holder in close proximity thereof, the spring having a front end restrained by the nose portion of the syringe body and a rear end under the enlarged head of the needle holder.

31. The tamperproof syringe of claim 30 wherein said nose portion has a wall defining an internal cavity extended in the direction of retraction which closely confines the spring and thereby facilitates assembling from the rear the needle holder and uncompressed spring into a compressed state in said nose portion.

32. The tamperproof syringe of claim 32 wherein an opening is provided in the front of the nose portion of the syringe body and a part of the stem portion of the needle holder extends outwardly through said opening in order to facilitate installation of the needle into the stem portion of the needle holder from the front of the syringe after the needle holder has already been assembled in the nose portion of the syringe body.

33. The tamperproof syringe of claim 28 wherein the ratio of the cross sectional areas of the variable chamber and the dislodgeable stopper is selected so that the maximum expected thumb force on the plunger during an injection will produce a pressure force which is slightly less than the amount of force necessary to dislodge the stopper or cause it to move significantly with respect to the plunger opening.

34. The tamperproof retractable syringe of claim 33 wherein said ratio of the cross sectional areas of the variable chamber to the area of the dislodgeable stopper is at least two to one so that at least twice the force to dislodge the stopper can be applied to the plunger during an injection without blowout of the stopper.

35. The tamperproof retractable syringe of claim 22 wherein the needle holder has an inner head and a separable retainer member surrounding the inner head that are coupled

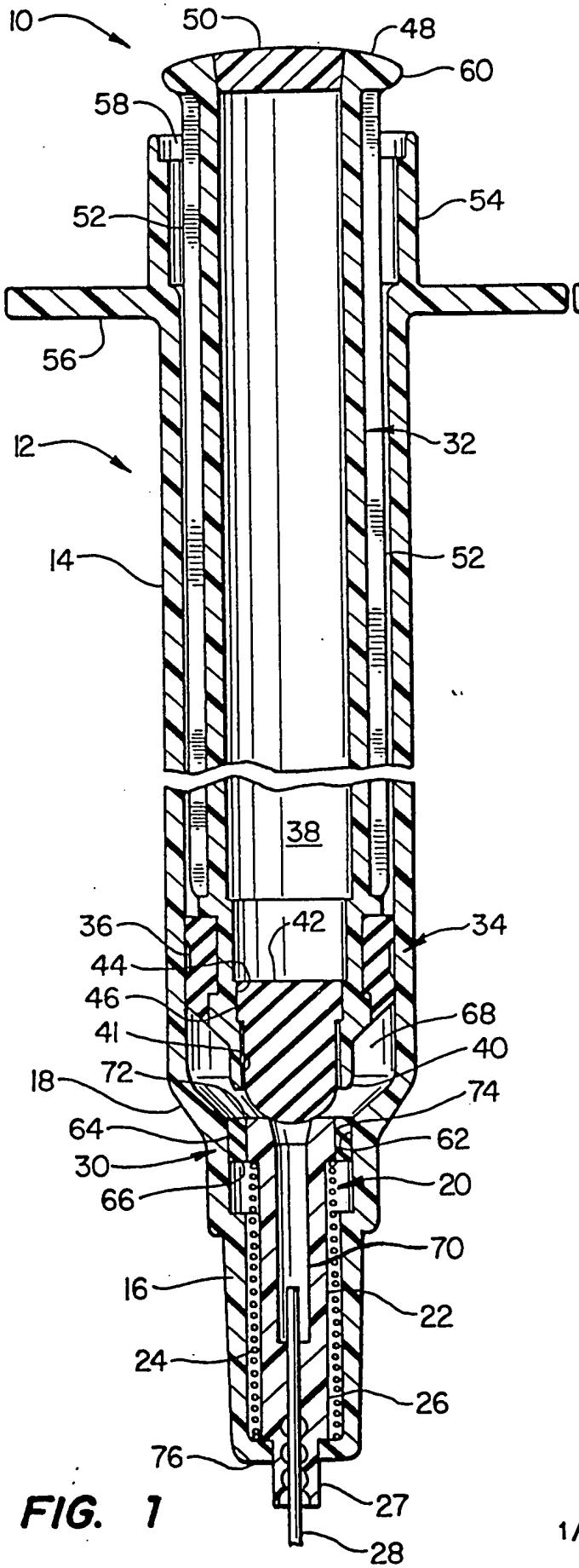

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FIG. 1

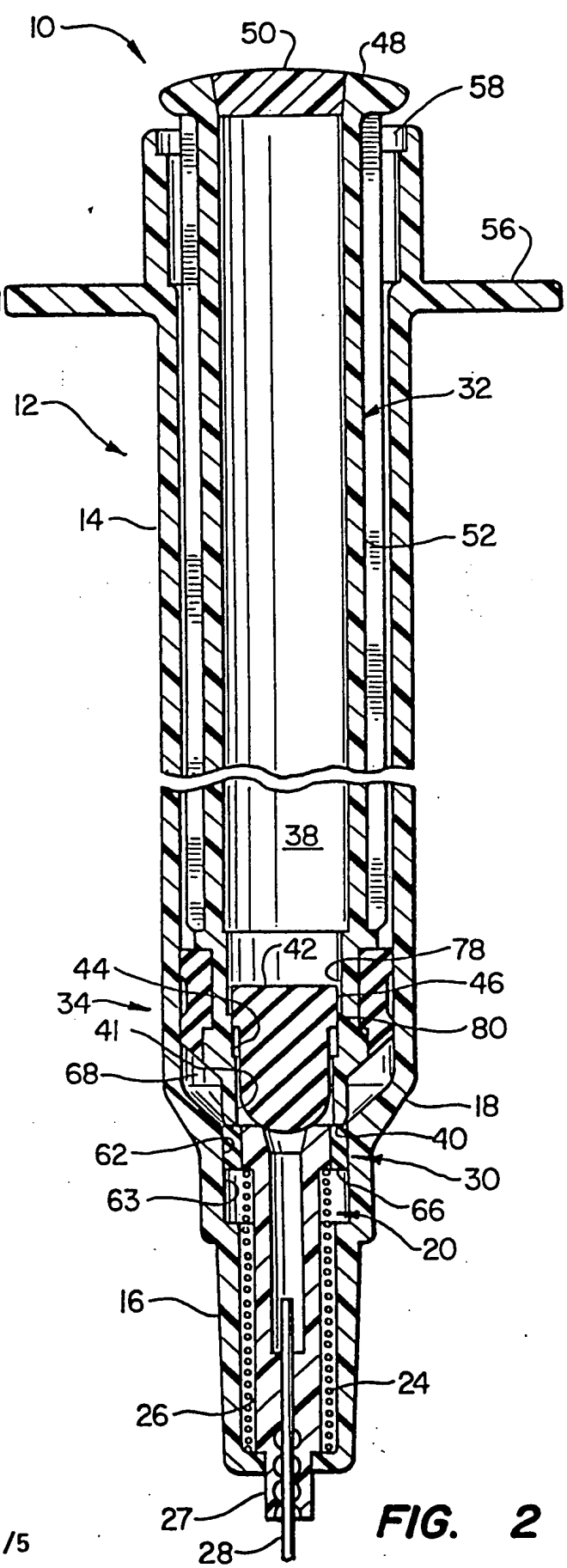
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FIG. 2

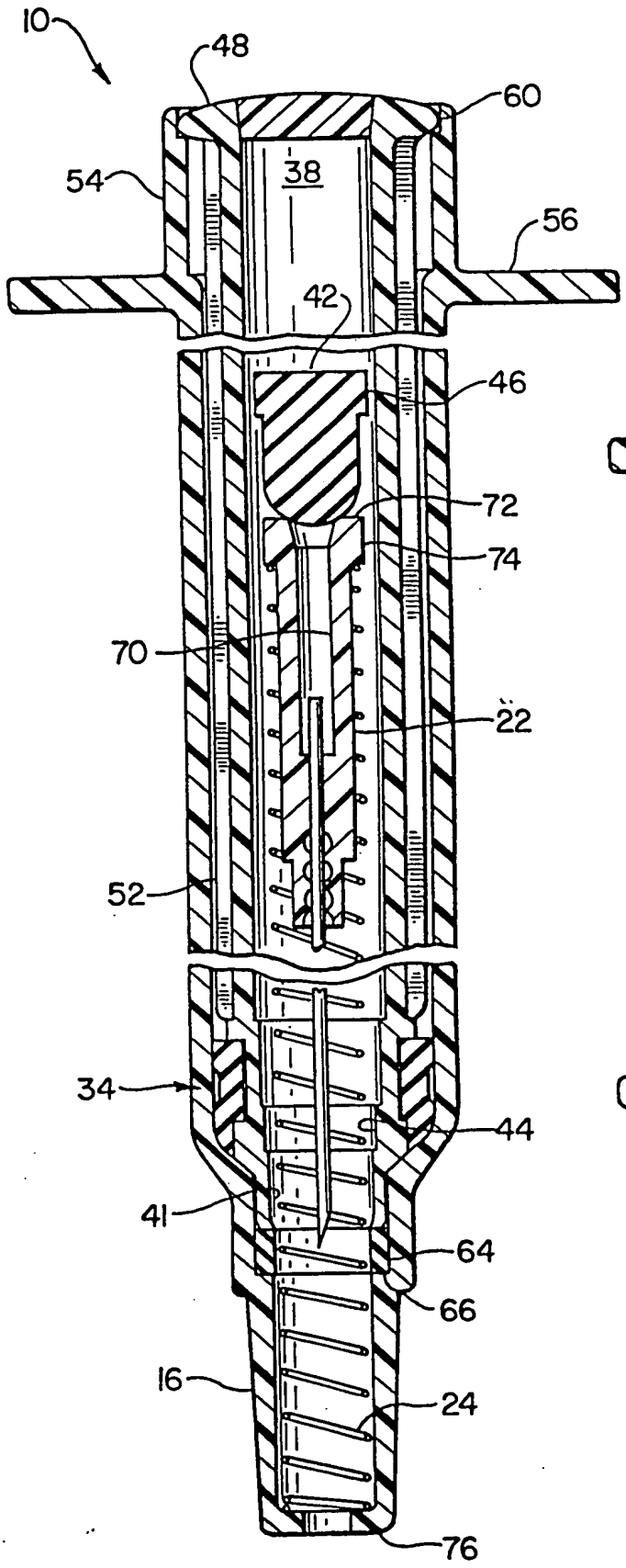


FIG. 3

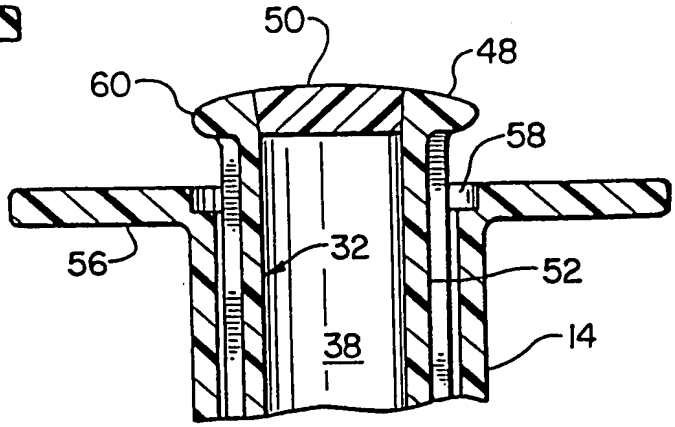


FIG. 4A

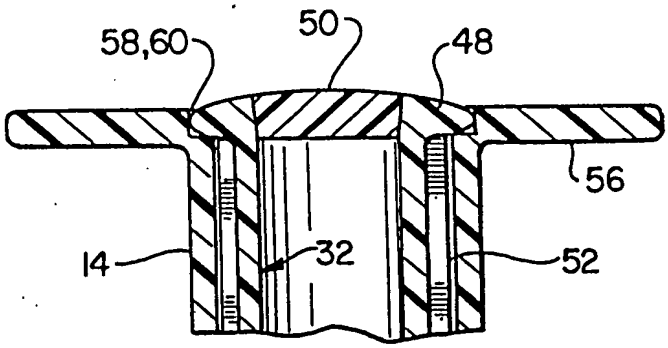


FIG. 4B

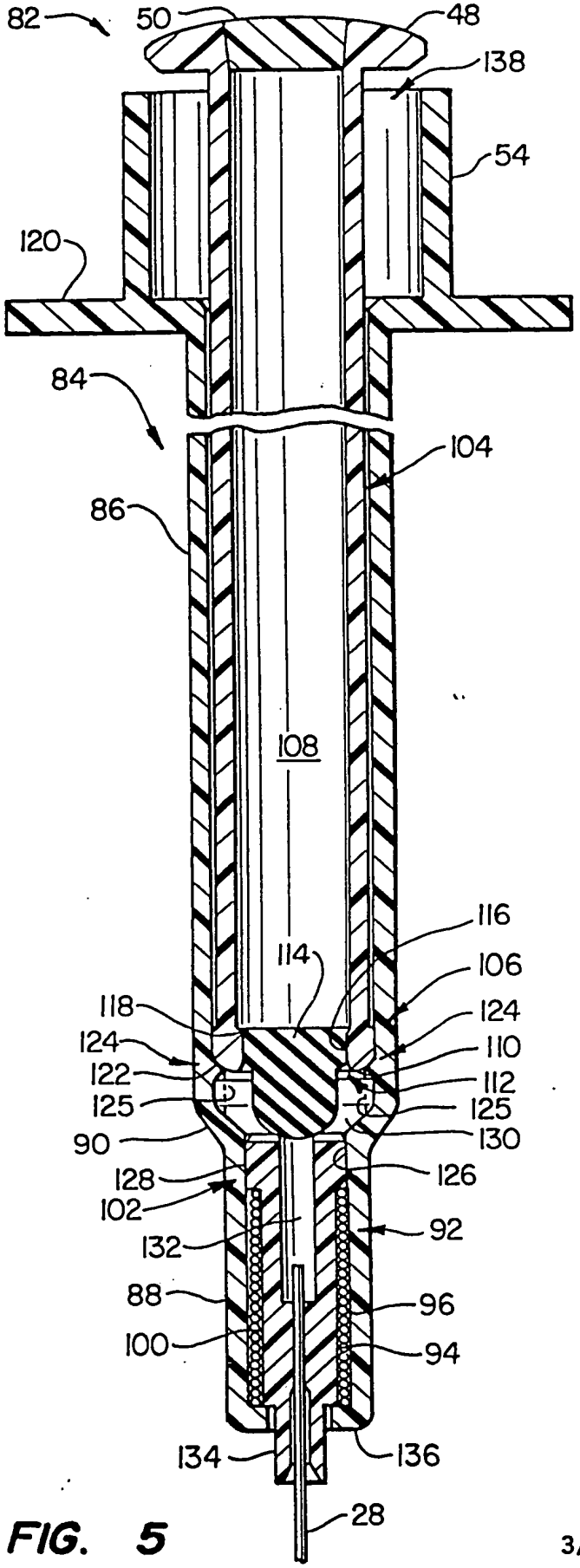
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FIG. 5

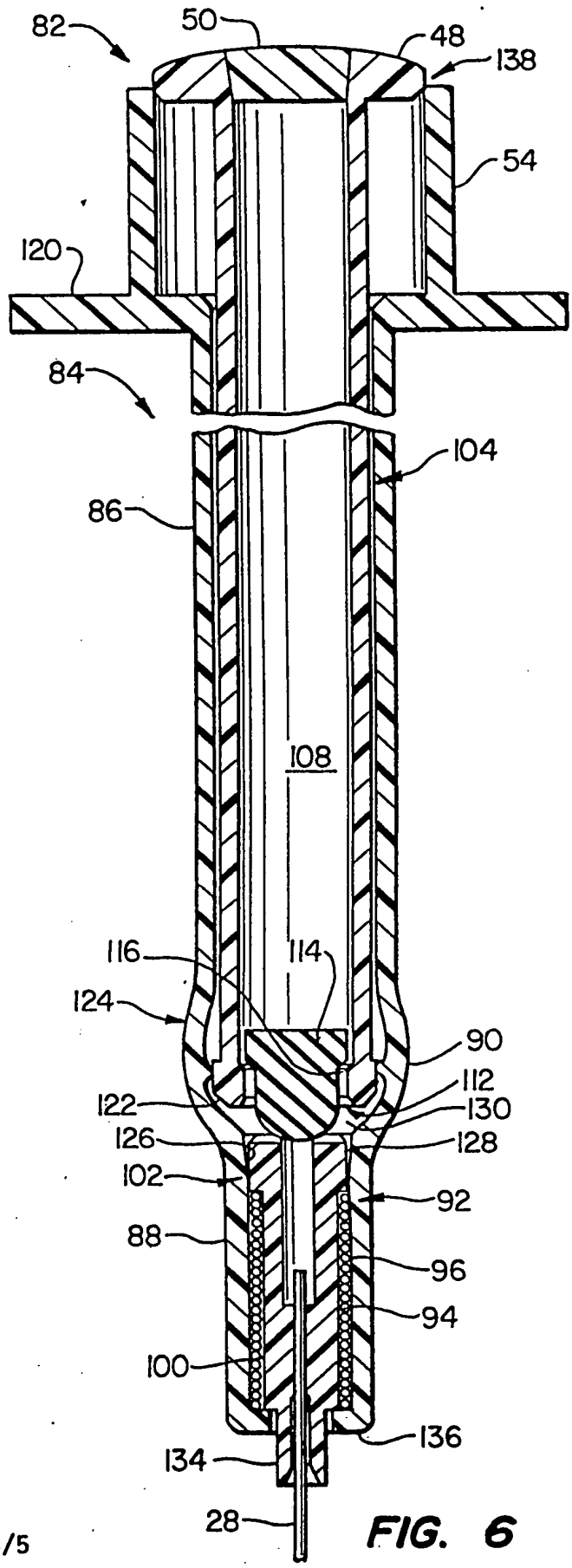
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FIG. 6

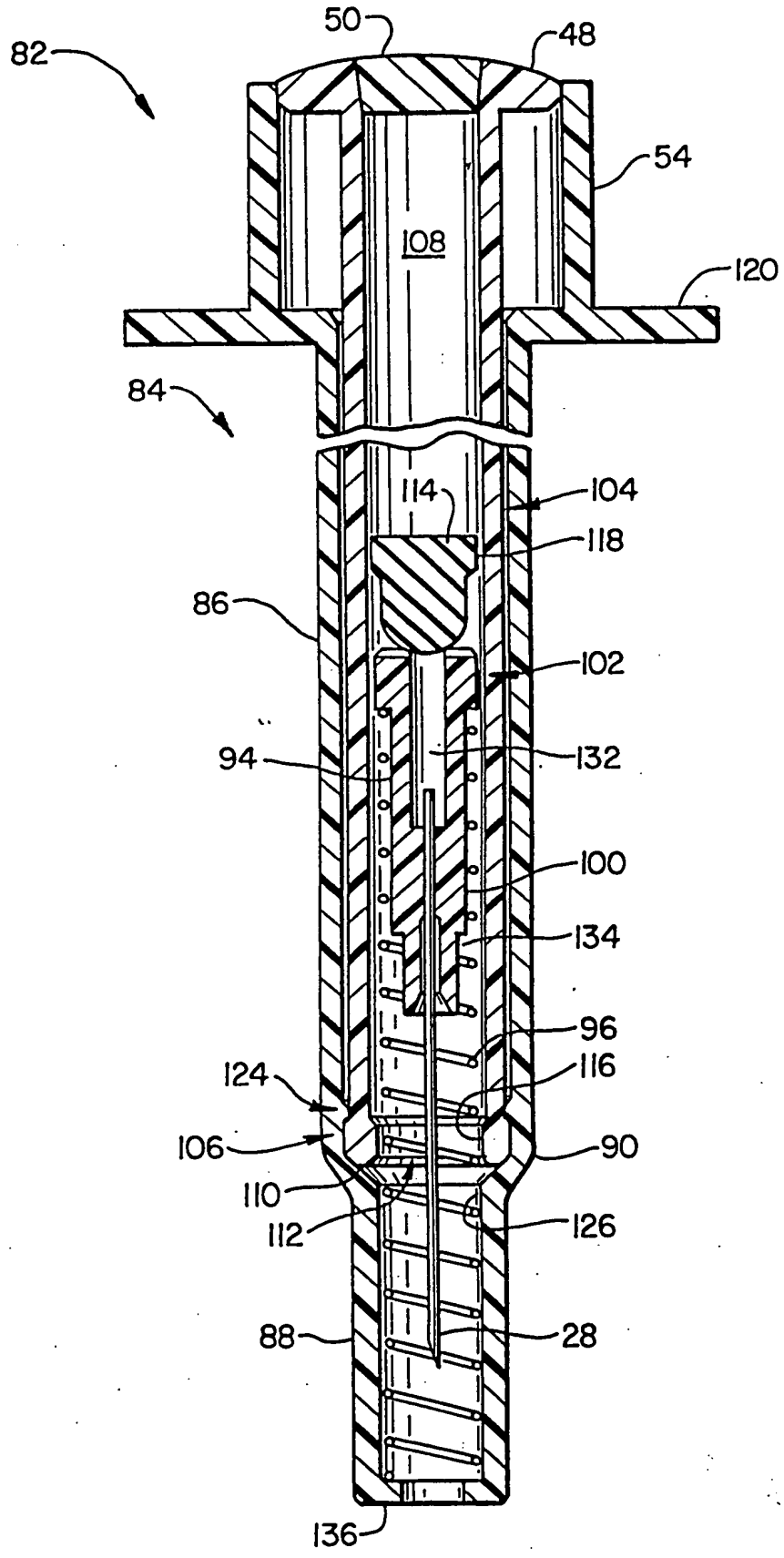
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FIG. 7

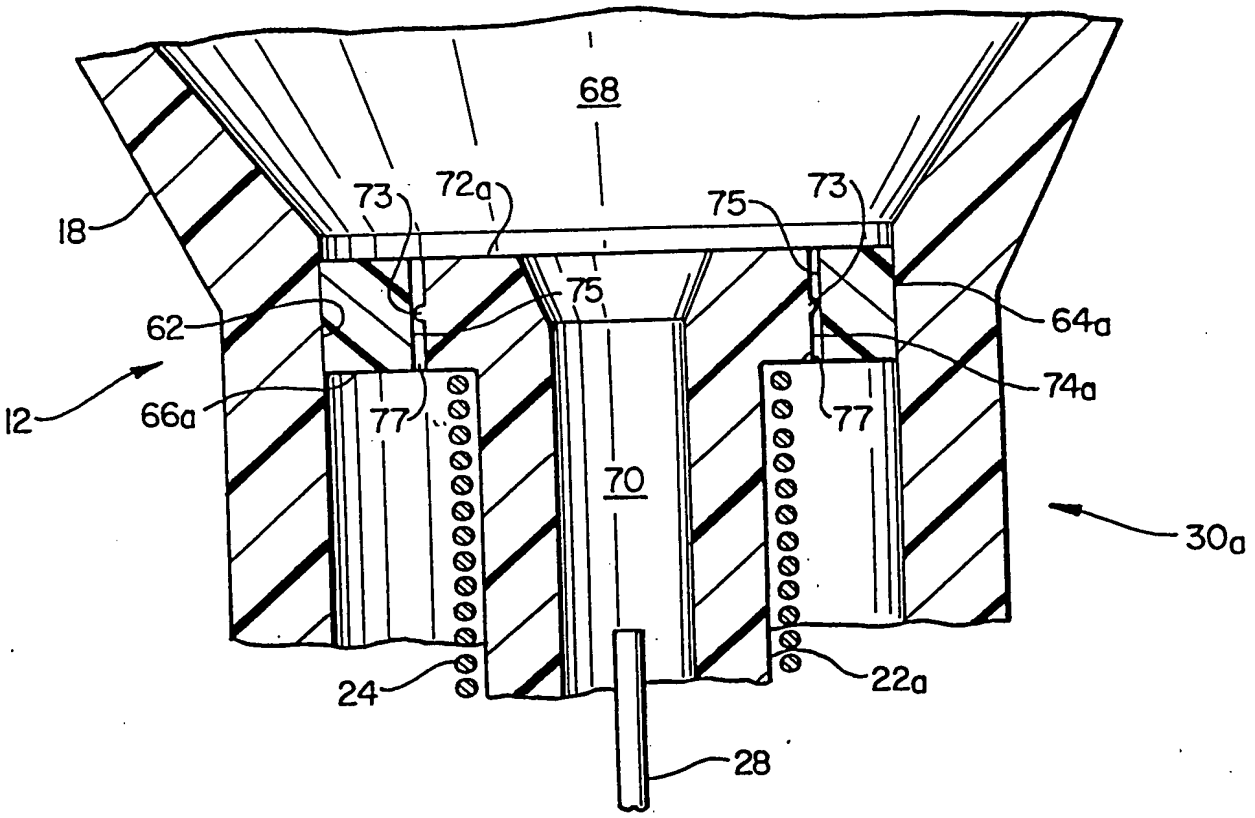


FIG. 8

# INTERNATIONAL SEARCH REPORT

International application No.
PCT/US96/05711

A. CLASSIFICATION OF SUBJECT MATTER
IPC(6) :A61M 5/00
US CL :604/110
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 604/187, 192, 195, 198, 218, 263

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|---|---|---|
| A | US, A, 4,994,034 (BOTICH ET AL.) 19 February 1991, see entire document. | 1-36 |
| A | US, A, 5,114,410 (CARALT BATLLE) 19 May 1992, see entire document. | 1-36 |
| A | US, A, 5,180,370 (GILLESPIE) 19 January 1993, see entire document. | 1-36 |

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

| | | | |
|---|---|---|---|
| * | Special categories of cited documents: | "T" | later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention |
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| "L" | document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) | "&" | document member of the same patent family |
| "O" | document referring to an oral disclosure, use, exhibition or other means | | |
| "P" | document published prior to the international filing date but later than the priority date claimed | | |

Date of the actual completion of the international search
11 JUNE 1996

Date of mailing of the international search report
22 JUL 1996

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